UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTIONS IN LIMINE

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Plaintiffs Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this Reply in Support of Their Motions in Limine (ECF 342).

I. INTRODUCTION

As made clear in Defendants' Opposition to Plaintiffs' Motions in Limine, they are seeking to introduce evidence that is irrelevant and would be unfairly prejudicial, misleading, confusing, and a waste of time. Plaintiffs' Motions in Limine should all be granted.

Defendants have failed to address the applicable law supporting the conclusion that consumer perception evidence is not required, or to demonstrate any value the jury would garner from an implication that such evidence is required (Motion in Limine 1). Defendants can explore the bases and facts supporting Plaintiffs' experts' conclusions but should be prevented from improperly suggesting to the jury that Plaintiffs were required to have conducted scientific research or human clinical research on Prevagen, as no such requirement exists (Motion in Limine 2). Because Dr. Mindy Kurzer's opinions relating to Vitamin D are about whether Prevagen impacts cognition or memory, a conclusion she cannot draw, her testimony on Vitamin D should be excluded (Motion in Limine 3).

With regard to Motion in Limine 4, Defendants have failed to refute Plaintiffs' argument that testimony or argument regarding the FTC staff-issued document, Dietary Supplements: An Advertising Guide for Industry ("FTC Guidance" or "Guidance") would be irrelevant, constitute impermissible legal opinion, and/or serve only to confuse the jury. There would be no legitimate reason for such testimony or argument at trial, and it should be excluded. Defendants' opposition to Motion in Limine 5 mischaracterizes Plaintiffs' argument and vastly overstates the scope of the opinions Plaintiffs seek to exclude. Defendants, however, cannot hide the fact that

their experts based their opinions on the amount and type of evidence needed to substantiate the Challenged Claims only on impermissible grounds: the experts' flawed interpretations of federal law and/or the Guidance. Having failed to set forth a permissible basis for the challenged opinion in their reports, Defendants' experts should be precluded from offering that opinion at trial.

Defendants' opposition confirms that the purported "good faith" and "advice of counsel" testimony and argument Defendants would like to offer is irrelevant here where there is no need for Plaintiffs to prove an intent to deceive. Evidence and argument about good faith and the advice of counsel should therefore be excluded (Motions in Limine 6 and 7). The Court should also reject Defendants' attempts to compare their own research and advertising to generalizations about diverse products marketed for diverse purposes, and exclude evidence and argument relating to the research or advertising practices of other companies (Motion in Limine 8).

Defendants have provided no credible argument as to why the FDA's accelerated approval of the Alzheimer's drug Aduhelm or the approval of a settlement agreement in a private class action is relevant to the issues that will be before the jury in this case, and evidence on those topics should be excluded (Motions in Limine 9 and 10). Finally, the monetary relief being sought in this case is irrelevant to any issue before the jury and should be excluded (Motion in Limine 11).

II. MOTION IN LIMINE 1: DEFENDANTS SHOULD BE PRECLUDED FROM ARGUING OR OFFERING EVIDENCE THAT PLAINTIFFS HAVE NOT PROFFERED EXTRINSIC EVIDENCE ABOUT CONSUMERS, ADVERTISING, OR MARKETING

Defendants' Opposition to Plaintiffs' Motion in Limine 1 ignores this Court's previous, and correct, conclusion that "[t]he lack of evidence of consumer perception does not mean finding that the challenged statements were not misleading." Op. & Order on Mot. for Summ. J.

& Mot. to Exclude Expert Test. (ECF No. 331) at 16. The lack of consumer perception evidence is irrelevant to any issue before the jury and would serve only to mislead them into believing a legal requirement exists that does not. Defendants should therefore be precluded from introducing such argument or evidence at trial.

Defendants incorrectly argue that the jury must determine whether their advertising claims were express or implied. Defs.' Mem. of Law in Opp'n to Pls.' Mots. in Lim. and in Supp. of Defs.' Cross-Mot. to Preclude Pls. from Introducing References to Sales Data (ECF No. 359) ("Defs.' Opp'n Br.") at 6. The jury need not make such a factual determination. They need only determine if the claims were made. *See FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1188 (N.D. Ga. 2008) (identifying elements of proof for Plaintiffs' claims)*; FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957 (N.D. Ill. 2006) (same); *People v. Gen. Elec. Co., Inc.*, 756 N.Y.S.2d 520, 523 (App. Div. 2003) (same). In this case, the Challenged Claims are express or clearly and conspicuously implied. S*ee* Pls.' Mem. of Law in Supp. of Their Mots. in Lim. (ECF No. 343) ("Pls.' Opening Br.") at 5. The jury will either agree that the claims were made or they will not, and they do not need extrinsic evidence to interpret the plain message of Defendants' advertisements.

Despite Defendants' efforts to import an extrinsic evidence requirement from cases applying statutes that are not at issue here, the fact remains that extrinsic evidence is not a requirement. Indeed, the NYAG is not aware of any instance in which it has been required to produce consumer perception evidence. Thus, any argument that such evidence was required should be precluded from Defendants' presentation to the jury.

It is well established that if an advertisement makes an express claim or an implied claim that is reasonably clear on its face, then Plaintiffs are not required to put forth any extrinsic

evidence in form of consumer research or surveys. *See id.* Rather than address this clear, and applicable, case law, Defendants argue that there is a "well-developed line of cases" holding that New York General Business Law requires extrinsic evidence of consumer perception in order to prevail on false advertising claims. Defs.' Opp'n Br. at 4-5. This argument should be rejected. The cases Defendants cite in support of their argument address claims under the Lanham Act, the federal trademark statute. *Id.* at 5 (citing *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007); *Blue Buffalo Co. v. Nestle Purina Petcare Co.*, No. 4:15-cv-384, 2015 WL 3645262, at *7 (E.D. Mo. June 10, 2015)). Because these cases cite the Lanham Act, not the General Business Law, Defendant's characterization of them as a "well-developed line of cases" under the GBL is disingenuous at best. The GBL is modeled on the FTC Act, not the Lanham Act, and as such all the case law cited in Plaintiffs' opening Memorandum applies equally to the NYAG's GBL claims. Defendants have failed to address *any* of that applicable case law. *Compare* Pls.' Opening Br. at 4-6 (and authorities cited therein) with Defs.' Opp'n Br. at 5-7.

In any event, the Lanham Act cases cited by Defendants are not at odds with the proposition that Plaintiffs have advanced in support of their motion: extrinsic evidence is *not required* for claims that are explicit or clear. *Compare* Pls.' Opening Br. at 4-5 (noting that extrinsic evidence is not required where claims are explicit or where claims are clearly and conspicuously implied) *with* Defs.' Opp'n Br. at 5 (arguing that Lanham Act cases require extrinsic evidence where claims are "susceptible to more than one reasonable interpretation") (quoting *Time Warner Cable*, 497 F.3d at 158, and citing *Blue Buffalo*, 2015 WL 3645262, at *7). If the jury does not find that the claims challenged by Plaintiffs are explicit or clear, the jury will find that the claims were not made. The fact that there is no consumer perception data is irrelevant.

Defendants' cases are consistent with the concept outlined by Plaintiffs in their opening Memorandum: where claims are express or clearly and conspicuously implied, no extrinsic evidence is necessary for the fact finder to determine what claims were made. Defendants cite *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862 (E.D.N.Y. 2018), which applied different, and inapplicable, statutes and involved claims that had to be implied from the language that was actually used in the advertisements. Defs.' Opp'n Br. at 5-6. Specifically, the court was to consider whether the statement "immune support" conveyed a message that the product at issue could prevent or treat disease, and whether "The Better Vitamin C" slogan conveyed a message that the product was more easily absorbed than ascorbic acid. *See Hughes*, 330 F. Supp. 3d at 871 (applying California and Missouri law). Defendants similarly cite *Weaver v. Champion Petfoods USA Inc.*, 3 F.4th 927 (7th Cir. 2021), a case applying the Wisconsin Deceptive Trade Practices Act, in which the parties were attempting to show that the advertising term "biologically appropriate" conveyed the message that the product did not contain plastics and resins. *See id.* at 934-35. Defendants also cite *Vizcarra v. Unilever U.S., Inc.*, 339 F.R.D. 530 (N.D. Cal. 2021), a case in which the proposed class representative argued "that consumers understood the Vanilla Representations — which are comprised of the term 'natural vanilla,' and images of two vanilla beans, vanilla flowers, and a scoop of the ice cream with black specks — as indicating that the ice cream at issue would be flavored exclusively with vanilla from the vanilla plant." 339 F.R.D. at 547. Finally, Defendants cite *In re KIND LLC "Healthy & All Natural" Litig.*, 627 F. Supp. 3d 269 (S.D.N.Y. 2022), in which no objective definition of the advertising claim "All Natural" existed. *Id.* at 284. These cases illustrate the distinction between an arguably ambiguous, implied claim, and the claims at issue in this case, in which Plaintiffs

intend to establish, *inter alia*, that the language "Improves Memory" conveys that Prevagen improves memory.

Defendants incorrectly argue that Plaintiffs have admitted that certain Challenged Claims are vague and that Plaintiffs have also admitted that the term "clinical" is vague and ambiguous. Defs.' Opp'n Br. at 6 (citing ECF No. 257). Defendants cite to Plaintiffs' Counterstatement of Material Fact ¶ 89, in which Plaintiffs stated that "[t]he term, 'clinical,' **as used,** is vague and ambiguous" in response to Defendants' statement that "[b]etween approximately May 2008 and January 2009, Quincy conducted an open label clinical trial (the 'Open Label Trial') consisting of approximately 55 adult participants to assess the impact of apoaequorin on general health and quality of life, including cognitive function." (ECF No. 257 (emphasis added)). Plaintiffs' statement makes clear that they took issue with Defendants' use of clinical in the context of describing their open label study and this does not preclude a finding by the jury that use of the phrase "clinically shown" is unambiguous in the context of Defendants' advertisements. As Defendants acknowledge, "context is crucial" when determining whether an advertising claim is misleading. Defs.' Opp'n Br. at 7 (citing *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013)). Defendants' belief that "clinically shown" is susceptible to more than one meaning should not be binding on the jury because, as Defendants admit, it is squarely within the province of the jury to determine if Challenged Claims are made. *Id.* at 6. As such, the jury should be permitted to evaluate advertising using the phrase "clinically shown" to determine if those ads are misleading.

Finally, Defendants' "context is crucial" argument does not support their argument that consumer perception evidence is required. Defendants cite *Turk v. Rubbermaid*, No. 21-CV-270, 2022 WL 836894 (S.D.N.Y. Mar. 21, 2022), to argue that if a product's labelling directs a

consumer to another statement, that statement should be considered in evaluating whether the advertisement is deceptive. Defs' Opp'n Br. at 7. But it is well established that although an allegedly misleading statement must be viewed in light of its context on the product label or advertisement as a whole, a reasonable consumer should not be expected to look beyond the misleading representations on the front of a box to discover the truth in small print on the side of the box. *Mantikas v. Kellogg Co.*, 910 F.3d 633, 636-37 (2d Cir. 2018); *see also Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) ("Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings."). Thus, if a disclosure or disclaimer statement is hidden or illegible, then it is not sufficient to alleviate defendant's liability — and a factfinder is permitted to disregard that statement in determining the advertisement's overall message. *See People v. Orbital Publ. Group, Inc.*, 95 N.Y.S.3d 28, 29 (App. Div. 2019) (concluding, based on the advertisements at issue, that "[t]he disclaimer on the back of the solicitations is insufficiently prominent or clear to negate the overall misleading impression"); *see also Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26 (1995) (adopting objective definition of deceptive acts and practices, "which may be determined as a matter of law or fact (as individual cases require)"). Defendants' sole defense to their *Collins* disclaimer is that it is "not buried in large blocks of small print where consumers are unlikely to see it," Defs.' Opp'n Br. at 8, but this statement by Defendants does not foreclose a determination by the fact finder that this disclaimer is not sufficiently prominent and unambiguous.

Defendants have failed to address the applicable case law supporting the conclusion that extrinsic evidence is not required for explicit or clear and conspicuous advertising claims. They have also failed to demonstrate any value the jury would garner from an implication that extrinsic evidence is required, when it is not. Any argument or evidence regarding the lack of extrinsic consumer protection evidence should therefore be excluded.

III. MOTION IN LIMINE 2: THE COURT SHOULD REJECT DEFENDANTS' ATTEMPT TO REQUIRE PLAINTIFFS TO PUT FORTH SCIENTIFIC OR CLINICAL RESEARCH

Plaintiffs seek to preclude Defendants from arguing or introducing evidence that Plaintiffs have not conducted scientific research or human clinical research concerning apoaequorin or Prevagen. Pls.' Opening Br. at 7-8. Although Defendants concede that no such requirement exists, Defendants argue this evidence is relevant to "testing the credibility and strength of an expert's finding and opinion." Defs.' Opp'n Br. at 8. Defendants specifically point to Plaintiffs' expert, Dr. Jeremy Berg, and contend that they are entitled to ask "how he came to [his] conclusion" that Prevagen has not been shown to have any therapeutic effect on humans but has not conducted any research on apoaequorin. *Id.* at 10.

"Defendants have the burden of establishing what substantiation they relied on for their product claims," *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006), and this is the evidence that Plaintiffs' experts considered in reaching their opinions. Plaintiffs' experts, including Dr. Berg, offered opinions based on their review of Defendants' purported scientific evidence along with, in some instances, other research found from literature searches or results of any data analyses. All of this information was disclosed to Defendants during discovery. *See* Decl. of Mary Sano (ECF No. 295) Ex. 1, Sano Aff. Report ¶¶ 14-17; *id.* Ex. 2, Sano Rebuttal Report ¶ 2; Decl. of Janet Wittes (ECF No. 296) Ex. 1, Wittes Aff. Report ¶ 13; *id.* Ex. 2, Wittes

Rebuttal Report ¶ 2; Decl. of Jeremy Berg (ECF No. 297) Ex. 1, Berg Aff. Report ¶ 7; *id.* Ex. 2, Berg Rebuttal Report ¶ 1; Decl. of Peter Malaspina (ECF No. 298) Ex. 1, Malaspina Rebuttal Report ¶¶ 4-5. During cross-examination, Defendants, subject to any objections, could explore how Plaintiffs' experts formed their conclusions, test the strength of their findings, and question their credibility. However, questions about whether Plaintiffs' experts have conducted their own study on apoaequorin or Prevagen go beyond the bases for or facts supporting their proffered opinions, and are irrelevant. *See* Pls.' Opening Br. at 7.

Defendants rely on *In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), but *Mirena* is distinguishable. Defs.' Opp'n Br. at 9. In *Mirena,* the expert had worked on the regulatory review of the product at issue in the case, and plaintiffs sought to ask questions about her "personal recollections regarding the Mirena labeling process." 169 F. Supp. 3d at 471. The court in *Mirena* allowed the evidence to be elicited during cross-examination because it would be "impossible for a witness to divorce herself from her memories about what occurred during a project in which she was an active participant and segregate that information from the documentary record in forming her opinions." *Id.* However, in this case, exclusion of evidence concerning whether Plaintiffs' experts conducted studies on Prevagen or apoaequorin would not prejudice Defendants because no such studies were required and Plaintiffs' experts fully disclosed their opinions and the bases for them.

Defendants' attempts to characterize the fact that Plaintiffs' experts did not conduct any of their own scientific research on apoaequorin or Prevagen as a "concession" is a clear misstatement and should not be allowed. Defs.' Opp'n Br. at 9. Although Defendants admit that Plaintiffs were not required to have conducted any research, they seek to do just that — strongly imply that Plaintiffs were at fault for not conducting their own research. *Id.* at 8.

Not only is such evidence about whether Plaintiffs' experts conducted studies on apoaequorin or Prevagen irrelevant, it is substantially outweighed by unfair prejudice and confusion to the jurors. *See* Pls.' Opening Br. at 7-8. Such evidence would only serve to confuse the jury that Plaintiffs were required to have conducted such studies on apoaequorin or Prevagen. Plaintiffs would be unfairly prejudiced because the jury would then expect evidence, which would not be presented at trial. The Court should exclude evidence and argument that Plaintiffs have not conducted scientific research or human clinical research concerning apoaequorin or Prevagen from trial.

IV. MOTION IN LIMINE 3: DR. KURZER'S TESTIMONY RELATING TO VITAMIN D SHOULD BE EXCLUDED

Because Dr. Kurzer conceded that she is not an expert in the field of cognitive function and cannot testify on whether Prevagen impacts memory or cognition, Plaintiffs seek to exclude her testimony relating to Vitamin D since it would be irrelevant, cause unfair prejudice, mislead the jury, and waste time. *See* Pls.' Opening Br. at 8; *see also* Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19 (holding that Dr. Kurzer "may not draw an ultimate conclusion as to whether Prevagen impacts cognition or memory"); Wone Decl. Ex. 1, Kurzer Dep. Tr. at 39:9-12. In response, Defendants contend that this evidence should not be excluded because "Dr. Kurzer does not opine on whether Prevagen impacts memory or cognition," Defs.' Opp'n Br. at 11 (emphasis omitted), but this assertion is belied by Dr. Kurzer's own words. Her report concluded that "a supplement containing 500-1000 IU/day [of Vitamin D] would be sufficient to achieve cognitive benefits. All varieties of Prevagen that are currently available for sale (and have been available for sale since 2016) have 50 mcg, or 2000 IU [of Vitamin D] and consumers are directed to take one capsule or chewable per day." Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 78, 83; *see also* Wone Decl. Ex.

1, Kurzer Dep. Tr. at 269:25-270:12 (stating that the reference in her report to "cognitive benefits" includes memory). Furthermore, the report is replete with instances where Dr. Kurzer states that Vitamin D, which is essentially no different in this context than saying Prevagen, affects various aspects of cognitive function. *See, e.g.*, Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 61-70, 71, 76. In her deposition, Dr. Kurzer again affirms that based on the studies cited in her report, "vitamin D supplementation will help with cognitive benefits, including memory." Wone Decl. Ex. 1, Kurzer Dep. Tr. at 270:19-271:23; *see also id.* at 258:22-259:9 (relying on a study because it reflects "the totality of the evidence showing that vitamin D seems to have an impact on cognitive function and brain function").

Next, Defendants attempt to characterize Dr. Kurzer's testimony as an evaluation of the scientific literature "on the effects of Prevagen on brain function and cognition" in order to "formulate [her] expert opinion as to whether or not the studies constitute 'competent and reliable scientific evidence' in support of the claims at issue." Defs.' Opp'n Br. at 11 (brackets in original, internal quotation marks omitted). But this purported distinction is meaningless because Dr. Kurzer is not simply commenting on the quality of a study, i.e., how it was conducted.[1] Rather, she evaluated the "scientific literature[] on the effects of Prevagen on brain function and cognition" to reach a conclusion about whether it supports the ultimate claims at issue — whether Prevagen affects memory or cognition. Defs.' Opp'n Br. at 11 (internal quotation marks and emphasis omitted); *see also* Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 71-72, 78; Wone Decl. Ex. 1, Kurzer Dep. Tr. at 270:19-271:23. For example,

[1] The Court's prior order allows Dr. Kurzer to opine on the quality of a study or whether a study was conducted in a competent and reliable manner, but not on whether the results of a study show an impact on cognition or memory. Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19.

Dr. Kurzer identifies "[p]rospective studies that show beneficial associations between higher vitamin D intake and cognitive function" and then describes how these studies purportedly show that Vitamin D improved different aspects of cognitive function. Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 67, 72 (stating that "76-77% of the papers reviewed showed a statistically significant beneficial association between vitamin D and cognitive function"); s*ee also id.* ¶¶ 63-66, 68-69. The basis for Dr. Kurzer's opinion is her interpretation of the scientific literature about the effects of Vitamin D on cognitive function, and her opinion that these same Vitamin D studies constitute competent and reliable scientific evidence in support of the claims at issue is akin to saying that Prevagen impacts memory or cognition. Defendants' contention that Dr. Kurzer's opinions are not about whether Prevagen impacts memory or cognition is just an attempt to get around the Court's Order that Dr. Kurzer cannot testify about whether Prevagen impacts cognition or memory. Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19. The Court should reject Defendants' argument and exclude Dr. Kurzer's testimony on Vitamin D. *See* Pls.' Opening Br. at 8-9.

Dr. Kurzer's testimony about Vitamin D should also be excluded because, even if there were probative value, it would be substantially outweighed by the danger of misleading the jury, causing unfair prejudice, confusing the issues, and wasting time. *See id.* at 9-11. Defendants contend that Dr. Kurzer's testimony could be addressed through cross-examination and objections at trial, Defs.' Opp'n Br. at 12-13, but that would be inadequate. In support of her conclusion that Vitamin D provides cognitive benefits, Dr. Kurzer cites many scientific studies and discusses how these studies show benefits for cognitive function. Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 71-78. For example, Dr. Kurzer opines that "[t]he weight of the cross-sectional data (26 out of 34 studies) clearly supports a beneficial association between

vitamin D and cognition" and that "50% [of the RCTs] show benefits of vitamin D on cognition." *Id.* ¶ 74. Dr. Kurzer's voluminous testimony would waste time, as well as be unfairly prejudicial, misleading, and confusing to the jury who would be led to believe that Dr. Kurzer was, in fact, concluding that Prevagen impacts memory or cognition. The Court should exclude testimony by Dr. Kurzer involving Vitamin D. *See, e.g.*, *Nimley v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005) ("'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009) (noting that the jury would already have to "digest difficult scientific evidence and terminology" and excluding expert evidence in part because the probative value was substantially outweighed by the corresponding waste of time, danger of confusion, and unfair prejudice).

V. MOTION IN LIMINE 4: THE COURT SHOULD PRECLUDE TESTIMONY AND ARGUMENT REGARDING THE GUIDANCE OF THE FTC STAFF ON DIETARY SUPPLEMENT ADVERTISING

Defendants fail to refute Plaintiffs' argument that testimony or argument regarding the FTC staff-issued document, Dietary Supplements: An Advertising Guide for Industry would be irrelevant, constitute impermissible legal opinion, and/or serve only to confuse the jury.

A. Relevance

Defendants fail to show how testimony regarding the Guidance — a document that provides a general explanation of the law applying to *all claims* for all dietary supplement products — would be relevant to whether Defendants possessed sufficient scientific support for the *specific claims* at issue in this case. In opposing Plaintiffs' motion, Defendants recycle the

argument from their *Daubert* motion that Plaintiffs are attempting to hold them to a higher substantiation standard than the Guidance requires. *See* Defs.' Opp'n Br. at 14. As the Court stated in its order regarding Defendants' *Daubert* motion, however, "[t]hat argument misses the mark. The critical question for trial does not turn on an interpretation of the FTC Guidance." Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. at 15. The Court explained further that "[t]he question for trial is whether defendants had the necessary scientific evidence to support the claims defendants made while advertising Prevagen," a question that would be answered by experts in the relevant field. *Id.* In this case, because Defendants claim that Prevagen improves memory, provides cognitive benefits, and is clinically shown to have those effects, the relevant scientific fields are memory, cognition, and clinical trials. *See Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186 (stating that the competent and reliable scientific evidence standard "is context specific and permits different variations . . . *depending on what pertinent professionals would require for the particular claim made*" (emphasis added)). The specific standards of those fields, against which Defendants' substantiation materials must be measured, are not set forth in the Guidance. Therefore, any testimony regarding the Guidance and its contents would not be relevant to the issue of Defendants' liability for the claims at issue.

Defendants' description of their anticipated witness testimony regarding the Guidance only bolsters Plaintiffs' argument. Defendants, for example, state that their "fact witnesses will testify that they reviewed the FTC Guidance to assist them in developing scientific substantiation." Defs.' Opp'n Br. at 17. Whether Defendants reviewed the Guidance when developing their substantiation, however, is not at all relevant to whether that substantiation *is*

sufficient to support the Challenged Claims.[2] Defendants state also that their expert witnesses would "testify that Quincy has amassed sufficient scientific evidence in accordance with the FTC Guidance." *Id.* This statement only makes clear that Defendants continue to confuse the relevant *legal* standard with the relevant *scientific* standard. The Guidance constitutes a general explanation of federal advertising law. It does not set forth or explain the standards of the scientific fields at issue in this case. Testimony of Defendants' expert witnesses regarding the Guidance, therefore (in addition to being improper commentary on the legal standard), would not be relevant to, or help the jury understand, the standards of the relevant scientific fields.

Defendants also apparently attempt to establish the relevancy of the Guidance by stating that it is "admissible for the separate, independent reason that it is an admission of a party opponent." *Id.* at 15. Whether evidence is a party admission, however, relates only to the issue of whether that evidence constitutes hearsay. *See* Fed. R. Evid. 801(d)(2) (defining a party admission as non-hearsay). Party admissions are not automatically admissible; rather, they just are not inadmissible because of the rule against hearsay. *See* Fed. R. Evid. 802 (providing that hearsay is inadmissible unless provided otherwise by, *inter alia*, the federal rules). All evidence, including party admissions, must be relevant to be admissible. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."); *Asanjarani v. City of New York*, No. 09 Civ. 7493 (JCF), 2011 WL 6811027, at *1 (S.D.N.Y. Dec. 27, 2011) ("In order to be admissible, evidence must be

[2] As discussed *infra* at Section VII, testimony that Defendants reviewed the Guidance "to assist them" in developing substantiation would be relevant only to an argument that Defendants acted in "good faith" when developing substantiation and disseminating their claims. As Defendants themselves have acknowledged, however, good faith is not a defense to liability in this matter (Defs.' Opp'n Br. at 26), and Plaintiffs have moved to exclude all testimony and argument related to good faith from the proceedings to establish liability. Pls.' Opening Br. at 17-19.

relevant."). Defendants' party admission argument therefore does nothing to establish the relevancy or admissibility of testimony or argument regarding the Guidance.

Finally, Defendants' attack on Plaintiffs' cited case law does not help their cause. Defendants argue that none of the courts in the cited cases excluded the Guidance on relevancy or other grounds. Defs.' Opp'n Br. at 14-15. Plaintiffs, however, cited the cases for the specific proposition that the expert witnesses in this case need to apply the standards of the relevant scientific fields in order to assess the sufficiency of Defendants' scientific evidence. Pls.' Opening Br. at 12. As set forth above, because the Guidance does not set forth those specific scientific standards, testimony about it would be irrelevant.[3]

B. Legal Opinion

Defendants' argument that expert witness testimony regarding the Guidance would not constitute impermissible legal opinion shows only that Defendants fail to understand the relevant scientific fields in the case. Defendants argue that "[a]wareness and consideration of the FTC Guidance is required to understand the degree of scientific substantiation evidence typically required *in the dietary supplement industry* and to ensure that the experts' opinions are relevant to and consistent with the applicable standard." Defs.' Opp'n Br. at 16 (emphasis added). The standards against which Defendants' substantiation must be measured, however, are not those of the "dietary supplement industry," but rather the scientific fields implicated by the specific advertising claims at issue. *See, e.g.*, *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1387-88

[3] Defendants argue as well that "Plaintiffs have already stipulated to the admissibility and relevance of the Guidance, and it is included on the parties' Joint Exhibit List." Defs.' Opp'n Br. at 13. They make the same argument (*id.* at 34) as to the *Collins* settlement agreement, discussed *infra*. Plaintiffs included a number of documents, including the Guidance and the *Collins* settlement agreement, on the exhibit list to ensure they could use them on cross-examination, if necessary. Plaintiffs intend to remove the Guidance and the *Collins* settlement agreement from the Joint Exhibit List.

(M.D. Fla. 2018) (citing the opinion of the FTC's expert, a medical doctor and "expert in obesity treatment and weight loss," that "[t]o prove a weight-loss claim, 'experts in the field of obesity treatment and weight loss would require well-designed and properly conducted clinical trials'"; discrediting the opinion of defendants' proffered expert, a board-certified surgeon, as defendants had not established that he was "a pertinent professional or expert in the field of obesity treatment and weight loss"); *FTC v. COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1305, 1312 (D. Wyo. 2016) (finding, in case where FTC challenged claims that a dietary supplement could reverse and prevent graying of hair, that FTC's proffered witness was qualified to opine "on what experts *in the field of dermatology, specifically hair*, would require to constitute competent and reliable scientific evidence and whether Defendants' substantiation was sufficient to support the claims made") (emphasis added); *see also FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) (stating that, when FTC challenges claims as lacking a reasonable basis, "the FTC must: (1) demonstrate what evidence would in fact establish such a claim in *the relevant scientific community*; and (2) compare the advertisers' substantiation evidence to that required by the scientific community to see if the claims have been established") (cleaned up) (emphasis added); *FTC v. Braswell*, No. CV 03-3700 DT (PJWX), 2005 WL 4227194, at *10 (C.D. Cal. Sept. 27, 2005) ("The Court can look to what experts *in the relevant area of study* would consider to be adequate in determining the amount of and type of evidence that is sufficient" to substantiate claims) (emphasis added). As stated above, as Defendants have claimed that Prevagen improves memory, provides cognitive benefits, and is clinically shown to have those effects, the relevant scientific fields are memory, cognition, and clinical trials. The Guidance does not set forth the standards of those specific fields, nor does it specify how experts in those fields would come down on the issue of whether Defendants' claims are substantiated.

Rather, it sets forth an explanation of the *legal standard* in the case; accordingly, any expert testimony regarding its content would constitute impermissible opinion regarding the applicable law.

C. Juror Confusion

Defendants also fail in their effort to rebut Plaintiffs' argument that testimony concerning the Guidance would confuse the jury. Given that good faith is not relevant to liability, jurors could only be confused about the meaning and import of fact witness testimony that Defendants purportedly attempted to use the Guidance when developing substantiation. Jurors also would be confused by Defendants' scientific experts testifying about the Guidance's explanation of the legal standard, as the Court also would be instructing them on the law.

For the above reasons, Plaintiffs respectfully request that the Court grant its motion to exclude all testimony and argument regarding the Guidance.

VI. MOTION IN LIMINE 5: DEFENDANTS HAVE FAILED TO REBUT PLAINTIFFS' ARGUMENT THAT DEFENDANTS' EXPERTS SHOULD BE PRECLUDED FROM OPINING ON THE AMOUNT AND TYPE OF EVIDENCE NEEDED TO SUBSTANTIATE THE CHALLENGED CLAIMS

Defendants fail to rebut Plaintiffs' argument that Defendants' expert witnesses based their opinions on the amount and type of evidence needed to substantiate the Challenged Claims only on impermissible grounds: the experts' flawed interpretations of the law and/or the Guidance. Having failed to set forth a permissible basis for the challenged opinion in their reports, Defendants' experts should be precluded from offering that opinion at trial.[4]

[4] Plaintiffs' motion applies to all of Defendants' experts, despite Defendants' argument to the contrary. *See* Defs.' Opp'n Br. at 19 n.7. As none of Defendants' experts set forth a permissible basis for the opinion at issue in their reports, none of them can opine on the issue at trial. Plaintiffs' motion focused primarily on the opinions of Drs. Katz, Schwartz, and Wei because those experts opined on the issue most clearly. Plaintiffs did also note testimony of Dr. Gortler that would be excluded by the motion. Pls.' Opening Br. at 16 n.4.

Defendants attempt to oppose Plaintiffs' motion by mischaracterizing Plaintiffs' argument and vastly overstating the scope of the opinions Plaintiffs seek to exclude. Indeed, Defendants devote most of their opposition to discussing expert opinions that are not implicated by Plaintiffs' motion and attempting to explain how those opinions are not based (or not based solely) on an interpretation of federal law or the Guidance. Defendants, for example, discuss Dr. Katz's opinions about scientific support for a claim that apoaequorin "has a favorable risk-benefit profile" and whether it is appropriate to recommend Prevagen as an intervention to patients. *See* Defs.' Opp'n Br. at 20-21. Defendants refer as well to Dr. Schwartz's opinions regarding the use of the AD8 scale in the Madison Memory Study, subgroup analyses in studies, and potential mechanisms of action for Prevagen. *See id.* at 24. Defendants also discuss Dr. Wei's "statistical opinions." *See id.* at 25. Plaintiffs' motion, however, is not directed at any of these opinions. Rather, Plaintiffs' motion seeks to preclude Defendants' experts from testifying on a very specific and narrow topic: the amount and type of evidence needed to substantiate the Challenged Claims. Plaintiffs thus seek to preclude Defendants' experts from testifying, for example, that Defendants did not need a randomized, controlled trial ("RCT") to substantiate their claims, because that opinion is based only on an impermissible ground: the experts' beliefs that federal statutes and the Guidance do not require that type of trial. Defendants' references in their opposition to their experts' other opinions, and the bases thereof, cannot obscure the fact that the experts base their opinion on this specific issue only on their flawed understanding of the law. *See* Pls.' Opening Br. at 14-17.

Defendants also try to suggest that their experts based the challenged opinion, at least in part, on their education and experience. *See, e.g.*, Defs.' Opp'n Br. at 19 (stating that Defendants' experts relied on their "education, experience, and the prevailing views in their

respective fields" in opining on "the quantity and quality" of Defendants' substantiation). However, although Defendants' experts might have educational degrees and experience in the relevant fields, they did not base their opinions at issue on the standards of those fields. Dr. Schwartz, for example, despite having an educational background in neuroscience and psychology, never referenced or applied the standards of those fields in opining on what form of substantiation Defendants needed to support the Challenged Claims. Rather, as described in Plaintiffs' motion, he cites legal statutes and the Guidance as setting forth the applicable substantiation standards. *See* Pls.' Opening Br. at 15.

Finally, Defendants state that "there is nothing wrong with Defendants' experts considering the applicable legal and/or regulatory framework that governs the case." Defs.' Opp'n Br. at 19. Plaintiffs agree that mere consideration of that framework, while wholly unnecessary for scientific experts, would not render the experts' opinions inadmissible. Defendants' experts, however, did more than merely consider the framework; they made it the sole basis for the opinion at issue.

For the above reasons, Plaintiffs respectfully ask the Court to preclude Defendants' experts from opining on the amount and type of evidence needed to substantiate the Challenged Claims.

VII. MOTION IN LIMINE 6: TESTIMONY AND ARGUMENTS ABOUT GOOD FAITH SHOULD BE EXCLUDED

Good faith is irrelevant to the liability phase of this case. Accordingly, the Court should exclude testimony and argument about Defendants' purported good faith.

Defendants make no attempt to distinguish this case from *FTC v. Pioneer Enterprises*, in which the court granted the government's motion in limine and precluded witnesses from testifying about the defendants' "good faith," "lack of bad faith," and their "efforts to comply

with federal and state laws" on the grounds that such testimony would be irrelevant. No. CV-S-92-615, 1992 WL 372350, at *3-4 (D. Nev. Nov. 12, 1992). Nor do Defendants cite any cases at all in their combined opposition to Motions in Limine 6 and 7. *See* Defs.' Opp'n Br. at 26-28.

What Defendants do say in their opposition confirms that the Court should preclude testimony about any of Defendants' witnesses' subjective good faith, and argument concerning Defendants' good faith. Defendants reaffirm that any good faith affirmative defense is not relevant to the liability phase of this case. *See id*. at 26. Yet they also state (as discussed *supra*) that "Defendants' fact witnesses will testify that they reviewed the FTC Guidance to assist them in developing scientific substantiation — exactly what the FTC intended when it issued the FTC Guidance." *Id.* at 17. The FTC Guidance is an interpretation of FTC law. Graham Decl. Ex. F (ECF No. 225-6), FTC Guidance at QUI-FTCNY-00189206 ("Application of FTC Law to Dietary Supplement Advertising"). The testimony Defendants propose — essentially, testimony that Defendants' witnesses purportedly educated themselves on the law and attempted to follow it — is precisely the kind of testimony that the Court should preclude (for multiple reasons). There would be no purpose to such testimony other than to attempt to show Defendants' good faith, which is irrelevant here as intent to deceive is irrelevant to Defendants' liability. *See generally* Pls.' Opening Br. at 18 (citing cases); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 526 (S.D.N.Y. 2000) (corporate liability under the FTC Act); *FTC v. Moses,* 913 F.3d 297, 307 (2d Cir. 2019) (individual liability under the FTC Act); *People v. Gen. Elec. Co.*, 756 N.Y.S.2d 520, 523 (App. Div. 2003) (N.Y. Exec. Law § 63(12)); *People v. Wilco Energy Corp*., 728 N.Y.S.2d 471, 473 (App. Div. 2001) (N.Y. Gen. Bus. Law §§ 349, 350). The testimony that Defendants propose would serve only to confuse the issues, mislead the jury, prejudice Plaintiffs, and waste time. As in *Pioneer Enterprises*, testimony about "defendants' lack of bad faith or

intent" or "their efforts to comply with federal and state laws" should be precluded. 1992 WL 372350, at *3-4.

Defendants ignore Plaintiffs' explanation of the narrowness of this motion. *Compare* Defs.' Opp'n Br. at 27 *with* Pls.' Opening Br. at 17 n.5. Plaintiffs seek to preclude testimony and argument about purported good faith. In other words, Plaintiffs seek to preclude testimony and argument that Defendants believed they were complying with the law, that they lacked bad faith, that they lacked an intent to deceive, that they were acting in good faith, and as to the conclusion that they believed their advertising claims to be substantiated. *See also* Pls.' Opening Br. at 17 & n.5, 19. Defendants are incorrect in contending that Plaintiffs' request, "taken to its reasonable conclusion," could "preclude Defendants from presenting a defense altogether," or that Plaintiffs seek to exclude "*any mention* of Defendants' understanding of the basis for its advertising and marketing." Defs.' Opp'n Br. at 27 (emphasis in original). Granting Plaintiffs' motion would not prevent Defendants from presenting evidence (subject to objections on other grounds) concerning "how [Defendants] developed Prevagen" (*id.*), Defendants' efforts to conduct research and interpret data to develop support for advertising claims, the relationship between Defendants' research results and their advertising claims, or limited factual context relating to matters other than whether Defendants were acting in good or bad faith. Plaintiffs seek to exclude only what is plainly irrelevant: testimony and argument about whether Defendants had an intent to deceive.

Defendants appear to concede that they should not be allowed to present any legal argument that they acted in good faith to the jury. *See id*. at 26-27 (seeking to present "testimony" only and stating that a good faith affirmative defense is relevant only to the relief phase of this case). Defendants should also be precluded from presenting any testimony that

would form the predicate for such a good faith argument — e.g., that they educated themselves on the law and attempted to comply with it. Irrelevant discussion of whether or not Defendants acted in good or bad faith would only waste time, mislead the jury, prejudice Plaintiffs, confuse the issues, and distract from what is actually at issue in the liability phase of this case: "whether defendants had the necessary scientific evidence to support the claims defendants made while advertising Prevagen." Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 15. The Court should grant Plaintiffs' motion and preclude testimony and argument about good faith. *See Pioneer Enterprises*, 1992 WL 372350, at *3-4; Fed. R. Evid. 401-403.

VIII. MOTION IN LIMINE 7: EVIDENCE AND ARGUMENT ABOUT THE ADVICE OF COUNSEL SHOULD BE EXCLUDED

Presenting evidence and argument about the advice of counsel is tantamount to arguing that a defendant acted in good faith. All such evidence and argument should be precluded, particularly since Defendants used the attorney-client privilege as a shield against discovery.

Defendants confine their opposition to Motion in Limine 7 to a single paragraph (Defs.' Opp'n Br. at 28) and once again do not cite any cases or attempt to distinguish any of the cases that Plaintiffs cited. Defendants concede that they are not asserting an advice of counsel affirmative defense. *Id.* Indeed, as Plaintiffs previously explained, the advice of counsel is not relevant to the liability of any Defendant (including Individual Defendant Mark Underwood). Pls.' Opening Br. at 20 (citing cases); *FTC v. Cyberspace.com LLC*, 453 F.3d 1196, 1202 (9th Cir. 2006).

Defendants contend that they are "entitled to introduce evidence about the genesis of their advertising claims . . . and this factual narrative necessarily includes discussions with counsel." Defs.' Opp'n Br. at 28. This contention merely confirms that Defendants intend to invoke the advice of counsel improperly as an attempt to demonstrate their good faith, which, as

explained *supra*, is irrelevant to the liability phase of this case. In addition, Defendants should not be allowed to mention any purported discussions with counsel after having repeatedly blocked discovery on the basis of the attorney-client privilege. Pls.' Opening Br. at 20-21 (citing cases and blocked discovery); *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) ("the attorney-client privilege cannot at once be used as a shield and a sword"); *Troublé v. Wet Seal, Inc.*, 179 F. Supp. 2d 291, 304 (S.D.N.Y. 2001) (precluding evidence about advice of counsel from trial after defendant blocked discovery on the basis of attorney-client privilege).

Raising the specter of discussions with counsel would serve no purpose other than to confuse the issues, waste time, mislead the jury, and prejudice Plaintiffs. Fed. R. Evid. 401-403. As in *Pioneer Enterprises* (where the witnesses at issue were former counsel), this Court should preclude any evidence and argument concerning the advice of counsel from the liability phase of this case. 1992 WL 372350, at *3-4.

IX. MOTION IN LIMINE 8: EVIDENCE AND ARGUMENT RELATING TO THE RESEARCH OR ADVERTISING PRACTICES OF OTHER COMPANIES SHOULD BE EXCLUDED

This action concerns Defendants' conduct, not the conduct of third parties. Evidence and argument describing the research or advertising practices of other companies, including other dietary supplement companies, is therefore irrelevant and prejudicial and should be excluded. Specifically, Defendants should be precluded from presenting irrelevant and prejudicial evidence and argument describing what is "usual" or "unusual," "common" or "uncommon," "ordinary" or "not ordinary," "typical" or "not typical," and variations thereof, in the dietary supplement industry, and from drawing comparisons between what Defendants did and what is purportedly usual, common, ordinary, typical, or variations thereof, among other companies, including dietary supplement companies.

Defendants would have this Court adopt a circular standard: what regulated companies elect to do, or omit to do, sets the standard for substantiation. But that is not the standard. Allowing Defendants to submit the evidence and argument that is the subject of this motion would thus waste time, mislead the jury, confuse the issues, and prejudice Plaintiffs. The question for trial is "whether *defendants* had the necessary scientific evidence to support the claims defendants made while advertising Prevagen" — an "issue for experts in the field . . . ." Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 15 (emphasis added). The determination of that issue "depends on the match between the defendants' statements and the proof." *Id.*

Defendants propose, circularly, that the experts in the "relevant fields" in this case must understand the "ordinary practices of the dietary supplement industry" to opine on what constitutes competent and reliable scientific evidence in their fields. Defs.' Opp'n Br. at 28-29. Although Defendants do not go so far as to contend outright that the dietary supplement industry itself is a scientific field, they argue that different standards of practice apply to dietary supplements than to other types of products like drugs, seemingly based on concepts taken from FDA law and regulations. *See id.* at 30-31 (referring to the "substantiation landscape for the dietary supplement industry" and purporting to draw a contrast between standards for "drug trials" from "dietary supplement structure-function claims"); Metzinger Decl. Ex. 17 (ECF No. 360-17), FDA, Small Entity Compliance Guide on Structure/Function Claims (Jan. 2002) (explaining legal requirements of an FDA regulation, including definitions of "structure/function" claims and "disease" claims and explaining that "disease claims" require FDA pre-approval and may be made only for drug products approved by the FDA) (cited in Defs.' Opp'n Br. at 32).

But FDA law and regulations are not relevant to this case. *See, e.g.*, Pls.' Opening Br. at 26; *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) (FDA requirements and regulations "simply do not govern" in a case under the FTC Act); *see also FTC v. Wellness Support Network, Inc*., No. 10-CV-04879-JCS, 2013 WL 5513332, at *10 (N.D. Cal. Oct. 4, 2013) (FDA regulations are not relevant in a case brought under the FTC Act). Expert testimony about FDA law and regulations is irrelevant and prejudicial and has already been excluded. *See* Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 18-19 (prohibiting Defendants' experts from opining on "the development of the FDA regulatory scheme or on Congress' intent in passing certain laws, such as the Dietary Supplement Health and Education Act"). As the Court has explained, the "question for trial" is "whether defendants had the necessary scientific evidence to support the claims defendants made while advertising Prevagen" — and the determination of that question "depends on the match between the defendants' statements and the proof." *Id.* at 15. The question concerns the quality of Defendants' proof and the fit of that proof to the challenged claims, not whether Defendants' proof is or is not akin to what other companies have done.

The cases Defendants cite (in footnote 10 of their Opposition) are not to the contrary. Neither citation relates to substantiation; both involve analyses of what claims were conveyed by challenged advertising and marketing. In *Rooney v. Cumberland Packing Corp.* (cited in Defs.' Opp'n Br. at 30 n.10), the court took judicial notice of turbinado sugar packaging and dictionary definitions of the terms "raw" and "raw sugar" and granted a motion to dismiss a class action lawsuit brought under California law, commenting on the "common industry marketing of turbinado sugar as raw cane sugar" in concluding that "turbinado sugar" and "raw" on product packaging did not communicate implied claims that the sugar was unprocessed and unrefined.

No. 12-CV-0033-H DHB, 2012 WL 1512106, at *2, 4 (S.D. Cal. Apr. 16, 2012). *United States v. Bayer* (also cited in Defs.' Opp'n Br. at 30 n.10) was an out-of-circuit civil contempt action (in which the government was subject to a higher "clear and convincing evidence" standard than the "preponderance of the evidence" standard that applies in this case). No. CV 07-01(JLL), 2015 WL 5822595, at *6 (D.N.J. Sept. 24, 2015). The *Bayer* court noted that the challenged claims ("Promote Overall Digestive Health" and "Helps Defend Against Occasional Constipation, Diarrhea, Gas and Bloating") were "ubiquitous in the industry" for probiotics in construing the challenged claims. *Id.* at 5, 12. These citations say nothing in favor of the relevance of so-called industry practice in evaluating the "match between the defendants' statements and their proof." Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 15.

Not only do the practices of other dietary supplement companies have no bearing on the whether Defendants' proof matches their statements, but there is also a mismatch between Prevagen and the specific examples of other products Defendants' experts cite (as well as among the other products themselves), underscoring the irrelevance and lack of probative value of those cited examples. As previously explained, the diverse examples Defendants' experts cite in support of their contentions that other companies may not have conducted randomized clinical trials to support their advertising claims, or that other companies may use subgroup analyses to support marketing, involve vitamins and minerals (AREDS2, calcium supplements), L-Theanine, an herbal remedy (Kava Kava), probiotics, and plant compounds and extracts (Kava Kava, ResVitale Resveratrol, Life Extension Dopa-Mind, and ginkgo biloba) — all different from Prevagen and apoaequorin. *See* Pls.' Opening Br. at 22-23. Further, third-party products that Defendants' experts propose to discuss are marketed for diverse purposes unrelated to the challenged claims at issue here, including for macular degeneration, anxiety, digestive health,

and longevity. *Id.*[5] These diverse products, marketed for diverse purposes, are not similar to Prevagen and Defendants' challenged claims; nor are they particularly similar to each other.

This is a case about Defendants' conduct, not the conduct of other companies, including other dietary supplement companies. *See FTC v. Chemence, Inc.*, 209 F. Supp. 3d 981, 985 (N.D. Ohio 2016); Pls.' Opening Br. at 23-24 & n.6 (citing cases). Even if Defendants were able to show that their practices were typical of the industry (which is not at all clear, particularly given the diversity of the examples Defendants point to), that would be neither here nor there with respect to Defendants' liability. *Int'l Art Co. v. FTC*, 109 F.2d 393, 397 (7th Cir. 1940) (finding it "immaterial that competitors employ the same or similar methods. If such be the case, it would afford the basis for an argument that such competitors should be dealt with likewise, not that petitioners should escape."); Pls.' Opening Br. 23-24 & n.6. Instead, allowing Defendants to present evidence and argument about what research or advertising practices are common or uncommon among other companies in the dietary supplement industry would do exactly what the court in *In re Rezulin Products Liability Litigation* was concerned about when it excluded expert testimony about purported industry ethical standards under Rule 403: that the proposed testimony would introduce "alternative and improper grounds for decision on bases other than the pertinent legal standards." 309 F. Supp. 2d 531, 545 (S.D.N.Y. 2004). In *Rezulin*, the alternative and improper grounds were the purported ethical standards; here, they are purported

[5] Meanwhile, Defendants' experts cite no examples or support for the propositions that Defendants expended more effort or spent more money in conducting research on Prevagen than other companies have, or that other dietary supplement manufacturers rely on proprietary, unpublished data to support marketing claims. Graham Decl. Ex. P (ECF No. 225-16), Katz Rebuttal Report ¶ 29; Graham Decl. Ex. X (ECF No. 225-24), Schwartz Rebuttal Report ¶¶ 9, 20, 44; *see also* Pls.' Opening Br. at 22.

standards and practices for research and advertising in the dietary supplement industry.[6] Defendants' proposed testimony is irrelevant and prejudicial under Rules 401-403. The Court should grant Plaintiffs' motion and preclude Defendants from offering evidence and argument about "common" or "uncommon" research or advertising practices of other companies, including companies in the dietary supplement industry.

X. MOTION IN LIMINE 9: THE COURT SHOULD EXCLUDE ANY EVIDENCE OR ARGUMENT RELATING TO THE FDA'S APPROVAL OF THE DRUG ADUHELM

The FDA's recent decision to grant accelerated approval for the Alzheimer's drug Aduhelm is not only irrelevant to what is required to substantiate advertising claims for Prevagen under both New York state law and the FTC Act, but also is an exceptionally complicated issue on which Defendants' experts present only a small and skewed slice of the entire story.

Consumer protection agencies and the FDA have different missions and different considerations when it comes to evaluation of scientific evidence. The very fact that the FDA has an accelerated approval pathway, which was the route used to approve Aduhelm, demonstrates that the FDA weighs public policy considerations in addition to scientific evidence to allow for earlier approval of drugs that treat serious conditions. *See* Wone Decl. Ex. 2, FDA, *Accelerated Approval Program* (Nov. 27, 2023), https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program.

[6] Defendants attempt to distinguish *Chemence* and *Rezulin* with a mischaracterization of Plaintiffs' position (that Plaintiffs' goal is a "one-sided trial" in which Plaintiffs' but not Defendants' experts may opine on what constitutes competent and reliable scientific evidence in the relevant fields). Defs.' Opp'n Br. at 28-29. (Defendants do not attempt to distinguish the cases other than *Chemence* and *Rezulin* that Plaintiffs cited.) In addition, Defendants' suggestion that Plaintiffs have a "vendetta against the entire dietary supplement industry and seek to make an example out of Quincy" (*id.* at 31-32 n.11) is both inappropriate and absurd.

The FDA's prescription drug approval processes are not relevant to the instant case. *See*, *e.g.*, *Bristol-Myers*, 738 F.2d at 559 (FDA requirements and regulations "simply do not govern" in a case under the FTC Act); Pls.' Opening Br. at 26. Further, however, the accelerated approval of Aduhelm against the advice of an FDA advisory committee and many internal and external experts was viewed as both unusual and controversial. The FDA's decision is an outlier that is particularly inapposite for Defendants' intended comparison to what the FDA would typically require "for expensive and potentially dangerous prescription drugs intended for diseased individuals," and it is not "the perfect example" of anything. Defs.' Opp'n Br. at 33. For instance, two Committees of the U.S. House of Representatives conducted an 18-month investigation into the FDA's review and approval of Aduhelm, identified multiple irregularities in the process, and recommended that the FDA take several immediate actions to help restore public trust in the agency. *See* Wone Decl. Ex. 3, Press Release, Committee on Oversight and Accountability Democrats, *Maloney and Pallone Release Staff Report on Review, Approval, and Pricing of Biogen's Alzheimer's Drug Aduhelm* (Dec. 29, 2022), https://oversightdemocrats.house.gov/news/press-releases/maloney-and-pallone-release-staff-report-on-review-approval-and-pricing-of; Wone Decl. Ex. 4, The Staffs of the Committee on Oversight and Reform and Committee on Energy and Commerce (Dec. 2022), *The High Price of Aduhelm's Approval: An Investigation into FDA's Atypical Review Process and Biogen's Aggressive Launch Plans* ("Congressional Report"), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-12-29.COR%20%26%20E%26C%20Joint%20Staff%20Report%20re.%20Aduhelm.pdf.

The two Congressional Committees held multiple briefings with FDA and reviewed more than 500,000 pages of documentation from FDA and Aduhelm's manufacturer to understand

what occurred during the Aduhelm approval process, *see id*. at 2. It would be a waste of time, grossly misleading, and highly prejudicial to allow Defendants' experts to simply reduce this complicated and nuanced story — to which they have been merely outside observers — to summary conclusions, such as Dr. Katz's assertion that the story of Aduhelm is illustrative of "how the FDA drug approval process . . . works" (*see* Graham Decl. Ex. P (ECF No. 225-16), Katz Rebuttal Report ¶ 35). Drs. Katz and Schwartz provide no insight or information as to *why* the FDA in fact decided to approve Aduhelm despite the opinions of many experts advising against it, nor do they provide any details as to the methodology or specific facts of the Aduhelm clinical trials at issue that clearly distinguish them from the Madison Memory Study.[7]

Defendants are incorrect when they insist that the approval of a particular prescription drug by a federal agency not involved in this case, regulated under a distinct federal statutory scheme, resulting from a process found to be "rife with irregularities," is somehow relevant to this case and appropriate for the jury's consideration. *See* Congressional Report at 15. Even if it were relevant (it is not), the amount of explanation and detailed additional information that would need to be introduced to place the Aduhelm approval decision into its proper context would be distracting and a waste of time that would far outweigh any minimal probative value. Any evidence relating to Aduhelm should be excluded.

[7] For instance, the FDA granted accelerated approval of Aduhelm after considering three clinical trials of Aduhelm of durations between 54-78 weeks and that included a total of 3,481 patients with Alzheimer's disease. *See* Wone Decl. Ex. 5, FDA, *Drug Trials Snapshots: ADUHELM* (Nov. 27, 2023) (heading "Who participated in the clinical trials?"), https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-aduhelm. This is a far cry from the Madison Memory Study, a single trial involving only 218 participants that lasted 90 days. Further, under the FDA's accelerated approval process used for Aduhelm, the drug's manufacturer is still required to conduct a study to confirm the anticipated clinical benefit and the FDA could remove the drug from the market if a confirmatory study does not demonstrate such a benefit. *See* Wone Decl. Ex. 2, FDA, *Accelerated Approval Program* (Nov. 27, 2023), https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program.

XI. MOTION IN LIMINE 10: THE COURT SHOULD EXCLUDE REFERENCES TO ANY PRIVATE LITIGATION ARISING FROM THE ADVERTISING OF PREVAGEN, INCLUDING THE *COLLINS* CLASS ACTION AND SETTLEMENT

Defendants' opposition fails to establish even the threshold requirement of relevance of the *Collins* class action settlement to the jury's determination of the net impression of the advertising at issue in the instant case. The fact that the litigation underlying the *Collins* settlement involved many of the same advertising claims that are at issue in the instant case does not make the existence or content of the settlement relevant; the fact remains that there is no probative value to the fact that the Defendants agreed to make certain disclaimers pursuant to the settlement agreement.[8] While Defendants cite to several documents from the *Collins* action, none of them includes or refers to any specific findings by the judge as to the effectiveness of the two disclaimers in the settlement.

When the judge in *Collins* requested specific briefing on how the proposed injunctive relief provided any benefit (*see* Wone Decl. Ex. 6, Post-Hearing Administrative Order, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. July 2, 2020), ECF No. 153), Defendants provided no evidence relating the effectiveness of these proposed disclaimers that the

[8] To the extent that Defendants suggest that the existence of the *Collins* settlement moots the claims at issue in this litigation or precludes Plaintiffs from obtaining injunctive relief, they are incorrect. A private class action settlement, "though approved by the district court," does not bar a public enforcement action by state or federal government, "even though many of the same claims are included in both actions," because the enforcement action "implicates the public's interest as well as private interests, and therefore the remedial provisions sweep much more broadly." *California v. IntelliGender, LLC*, 771 F.3d 1169, 1173, 1177-78 (9th Cir. 2014) (discussing "the well-established principle that the government is not bound by private litigation when the government's action seeks to enforce a federal statute that implicates both public and private interests") (citation omitted); *see also EEOC v. Jefferson Dental Clinics, PA*, 478 F.3d 690, 699 (5th Cir. 2007) (holding that the EEOC serves a public interest different from that of private litigants such that the EEOC could seek its own injunctive relief); *People v. Applied Card Sys., Inc.*, 11 N.Y.3d 105, 125 (N.Y. 2008) (noting that a settlement with private parties will not preclude the New York Attorney General from pursuing an action for injunctive relief in the public interest).

judge could have considered. *See* Wone Decl. Ex. 7, Defendant's Supplemental Submission in Support of Preliminary Approval of Class Action Settlement, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. July 16, 2020), ECF No. 155 at 1, 6-7 (without citing to any evidence, Defendants represented that the disclaimers make clear that Quincy's advertising statements are based on results of relevant subgroups in the Madison Memory Study, and that the disclaimers provide meaningful injunctive relief by making clear that Quincy's clinical trial demonstrated a statistically significant benefit on the intended population). To the extent that the judge made a decision on the adequacy of the disclaimers in *hypothetical* future advertisements based upon his own interpretation of the disclaimer language, his opinion carries no more weight than that of any individual juror in this case, each of whom will be determining the meaning and net impression of *actual* advertisements containing the disclaimer.

Notably, because the parties in *Collins* reached a settlement before the expert discovery deadline closed, the judge in that case did not have the benefit of any expert testimony on the Madison Memory Study. *See* Wone Decl. Ex. 8, Amended Order Setting Civil Trial Date and Pretrial Deadlines, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. Mar. 16, 2020), ECF No. 115 (setting expert discovery deadline of July 10, 2020); Wone Decl. Ex. 9, Joint Motion for Stay of Claims Pending Approval of Settlement Proceedings and Notice of Class-Wide Settlement, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. May 28, 2020), ECF No. 136 (indicating that the parties reached an agreement in principle on May 26, 2020 and requesting a stay to finalize the agreement). By contrast, Plaintiffs' experts Dr. Mary Sano and Dr. Janet Wittes — who submitted expert reports in the instant litigation in 2021, after the *Collins* litigation was already concluded — have both opined that the subgroup analyses described in the disclaimers are not reliable evidence of efficacy. *See* Graham Decl. Ex.

T (ECF 225-20), Sano Report ¶¶ 71, 73 ("defendants' multiple *post hoc* analyses suggest an effort to artificially generate results that would support claims about the cognitive benefits of Prevagen for at least some subset of subjects after the study failed to show any benefits of Prevagen for the study population as a whole. . . . In my opinion, the limited positive results defendants report from select outcomes and select subgroups have no scientific validity . . . ."), and ¶ 105 ("the purportedly significant results defendant report in the AD8 0-1 and 0-2 subgroups, even if validly calculated using appropriate correction for multiple outcomes, do not reflect improvement in memory."); Graham Decl. Ex. AA (ECF 225-27), Wittes Report at ¶ 78(c)-(d) ("*Post hoc* data mining almost ensures that some nominally statistically significant differences emerge . . . . Analysis after applying statistical corrections typically used by experts show that the data did not provide reliable evidence that any subgroup of patients showed benefit on the Cogstate Research Battery as a whole or on any of the nine individual Cogstate Tests.").

Thus, even if these wordy and highly technical disclaimers are comprehensible by consumers — which was not a specific finding from the *Collins* litigation and Plaintiffs in no way concede — the disclaimers themselves are misleading, because the subgroup results from the Madison Memory Study are not reliable evidence of efficacy even just for those limited populations. The judge in the *Collins* action had to consider the accuracy and effectiveness of the disclaimers in a vacuum, without seeing the disclaimer in the actual ads in dispute in this case, and without hearing expert testimony as to whether the disclaimers reflect sound scientific principles of data analysis. There is no probative value in this case to the fact that the judge approved the *Collins* settlement with the disclaimers, and any evidence relating to the settlement or other private litigation should be excluded.

XII. MOTION IN LIMINE 11: THE COURT SHOULD EXCLUDE ANY MENTION OF MONETARY RELIEF AT THE JURY TRIAL

Defendants do not dispute that the monetary relief in this case is irrelevant to any issue before the jury. Defs.' Opp'n Br. at 38-39. For the reasons set forth at pages 32-36 of Plaintiffs' opening Memorandum, Plaintiffs' Motion in Limine 11 should be granted.

XIII. CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court grant their motions in limine.

Respectfully submitted,

Dated: December 20, 2023

FEDERAL TRADE COMMISSION

By: /s/ *Christine Lee DeLorme*

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of December, 2023, I have caused service of the foregoing Plaintiffs' Reply in Support of Their Motions in Limine to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: December 20, 2023

/s/ Christine Lee DeLorme
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